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10/551,024	09/29/2005	Menno Willem Jose Prins	NL 030339	8261

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EXAMINER	
HURST, JONATHAN M	

ART UNIT	PAPER NUMBER
4153	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,024	PRINS, MENNO WILLEM JOSE	
	Examiner	Art Unit	
	JONATHAN M. HURST	4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 September 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/29/2005 and 09/17/2007.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The following documents, US 6,465,257,US 2002/0166582, WO 91/16966, and EP 0180064, cited in the information disclosure statement filed on 09/18/2007 have been considered as part of the information disclosure statement filed on 09/29/2005

Specification

2. The abstract of the disclosure is objected to because it is not present on a separate page. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 recites the *use of* a method for fluid analysis. It is unclear exactly how the *use of* a method further limits said method or provides for further patent protection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6-18, and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by O' Connor et al. (US 6,481,453).

Regarding claim 1 O' Connor et al discloses A fluidic device (See Abstract), comprising a plurality of sample channels(See Fig. 4A 314A-314N, 320A-320N, and C 12 L 34-38), said sample channels having a sample fluid inlet (See C 12 L 31-38 where fluid is added it is inherent that there must be an inlet),

said sample channels being adapted to be filled through said inlet with a sample fluid to be analysed or treated in use of said device (See C 13 L 1-24 and C 5 L 9-11),

a flush fluid control means positioned at said plurality of sample channels downstream the location where the sample fluid is analysed or treated in said device (See Fig. 4B 313 and C 13 L 4-21),

said flush fluid control means having flush fluid inlet means (See Fig. 4B 310) and flush fluid outlet means (See Fig. 4B 311) in communication with said sample channels (See Fig. 4B 313, 314A-314N, and C 13 L 4-21),

and said flush fluid control means being adapted to control the fluid composition in said plurality of sample channels. (C 13 L 4-15 where displacement of first fluid with second fluid by increase in pressure controls the fluid composition in channel)

Regarding claim 2 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said fluid device is a microfluidic device, at least partly manufactured by micromachining methods. (See Abstract and C 1 L 32 -46)

Regarding claim 3 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said flush fluid control means controls said flush fluid content at said channel inlet by replacing a fixed amount of said sample fluid in said sample channels with flush fluid upstream said fluid control means. (C 13 L 4-15 where there is a displacement of first fluid with second fluid by increase in pressure)

Regarding claim 4 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said control means is a cross-over channel. (See Fig. 4A and 4B where control means 313 is a channel and crosses over channels 314A-314N and 320A-320N)

Regarding claim 6 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said fluid inlet and fluid outlet means of said fluid control means are inlet an outlet channels. (See Fig. 4B inlet 310 and outlet 311 connected to channel 313)

Regarding claim 7 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said inlet and outlet channels comprise valve means for controlling flush fluid communication through said inlet and fluid communication through said outlet channel. (See C 13 L 4-6 and L 24-28)

Regarding claim 8 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said device comprises pressure regulating means for controlling flush fluid communication through said inlet, fluid communication through said outlet channel and fluid flow through said sample channels. (See C 13 L 18-29 where valves are pressure regulating means)

Regarding claim 9 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device comprising at least one threshold being arranged in said sample channels upstream said flush fluid control means in the fluid flow direction of said sample fluid. (See Fig. 4A where membrane 304 is a threshold and Abstract where impedance region is a threshold)

Regarding claim 10 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said threshold is tuneable. (See C 8 L 18-25 where impedance is controlled depending on application and is thus tuneable)

Regarding claim 11 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said threshold is in each of said channels is controlled by a physical constriction, a fluidophobic or hydrophobic effect, an electric field, a temperature or light excitation. (See C 7 L 38-46 where a constriction is used)

Regarding claim 12 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said threshold is controlled by a common control for all channels. (See Fig. 4A where threshold membrane 304 is common to all channels)

Regarding claim 13 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein independent sample plugs are formed in said sample channels by said control means. (See C 5 L 29-31 and C 13 L 4-24)

Regarding claim 14 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said flush fluid is a gas or an inert liquid. (See C 7 L 54-66 where second fluid is a flush fluid)

Regarding claim 15 O' Connor et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said fluidic device is a diagnostic cartridge, a microfluidic chip, a lab-on-a-chip, a micro-total-analysis system, a biochip or a biosensor. . (See C 1 L 21-32 and C 2 L 16-34 where biological material is analyzed and thus device is a biosensor)

Regarding claim 17 O' Connor et al. discloses a method of generating independent fluid samples in a fluidic device for multichannel analysis (See Abstract and C 2 L 16-34), said method comprising the steps of flushing of a flush fluid control means with flush fluid such that independent sample plugs are formed in a multiple channels of said device, said sample plugs being separated by said flush fluid. (See C 13 L 4-24)

Regarding claim 18 O' Connor et al. discloses all the claim limitations as set forth above as well as the method wherein said flush fluid control means having flush fluid inlet means (See Fig. 4B 310) and flush fluid outlet means (See Fig. 4B 311) , said method further comprising the steps of

introducing sample liquid into said device through a sample fluid inlet into a plurality of channels, (C 13 L 1-3 and C 3 L65–C 4 L 3)

transporting said sample liquid across said flush fluid control means further into said channels until a threshold, (See C 13 L 1-3 and C 4 L 1-3)

opening of said flush fluid inlet means and flush fluid outlet means by means of said

valve means (See C 13 L 3-6), flushing of said flush fluid control means with a flush fluid (See C 13 L 8-11) ,

transporting said sample liquid in said channels and said flush liquid in said flush fluid control means across said flush fluid control means further into said channels. (See C 13 L 13-24)

Regarding claim 20 O' Connor et al. discloses all the claim limitations as set forth above as well as the method wherein after the step of flushing said flush fluid control means with a flush fluid, said flush-fluid inlet means and flush-fluid outlet means are re-closed by means of valve means, or said flush fluid is put under pressure for transporting said sample fluid into said channels. (See C 13 L 4-12 and L 24-29)

Regarding claim 21 O' Connor et al. discloses all the claim limitations as set forth above as well as the method wherein said multichannel analysis is performed in a diagnostic cartridge, a microfluidic chip, a lab-on-a-chip, a micro-total-analysis system, a biochip or a biosensor. (See C 1 L 21-32 and C 2 L 16-34 where biological material is analyzed and thus device is a biosensor)

Regarding claim 22 O' Connor et al. discloses all the claim limitations as set forth above as well as the method wherein said multichannel analysis is performed by a microfluidic device. (See Abstract and C 1 L 11-32 and C 2 L 16-33)

Regarding claim 23 O' Connor et al. discloses a computer-readable medium having embodied thereon a computer program for processing by a computer (See C 8 L 35-43 where a computer is used to control a device it is inherent that said computer contains some form of program contained on a computer readable medium in order to allow the computer to perform said control) for generating independent fluid samples in a fluidic device for multichannel analysis (See C 8 L 12-43) the computer program comprising a code segment for flushing of a flush fluid control means with flush fluid such that independent sample fluid plugs are formed in a multichannel array of said device, said sample plugs being separated by said flush fluid. (See C 13 L 1-30 and See C 8 L 12-43 where there is a flushing of a flush fluid control means with flush fluid and subsequent formation of sample plugs formed by a pressure differential where said plugs are separated by said flush fluid. This formation of plugs is controlled at least in part by the operation of valves in the device said valves and thus pressure differential and flush fluid are controlled by a computer which must contain a program with code segments capable of causing a computer to perform these actions as stated above.)

Regarding claim 24 O' Connor et al. discloses a use of a method for fluid analysis, fluid synthesis, or the parallel synthesis of chemical compounds. (See C 13 L 23-25 where further fluid processing or analysis is performed)

7. Claims 1-2, and 4-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Manz et al. (US 6,540,896)

Regarding claim 1 Manz et al. discloses a fluidic device (See Abstract), comprisinga plurality of sample channels (See Fig. 2A-2D where there are a plurality of channels and Fig. 3B where 318 and 322 represents a plurality of channels for carrying a sample), said sample channels having a sample fluid inlet (Where fluid is added it is inherent that there must be an inlet),

said sample channels being adapted to be filled through said inlet with a sample fluid to be analysed or treated in use of said device (See C 7 L 22-32 where channels are filled form inlet with sample to be analyzed),

a flush fluid control means positioned at said plurality of sample channels downstream the location where the sample fluid is analysed or treated in said device (See Fig. 2A-2D where 200 controls a flow of multiple fluids and Fig. 3B where open field 304 controls flow of multiple fluids entering device),

said flush fluid control means having flush fluid inlet means (See Fig. 3B 316a and 318a) and flush fluid outlet means (See Fig. 3B 316b) in communication with said sample channels (See C 7 L 22-32 and Fig. 3B where inlet and outlet are in communication with channels 318 and 322),

and said flush fluid control means being adapted to control the fluid composition in said plurality of sample channels. (See Fig. 2A-2D where control means 200 controls composition of fluid in channels where there is a mixing of two fluids and subsequent

flow into channels. Also See C 8 L 9-16 where open field is fluid control means and directs plugs to channels 322 changing the chemical composition in said channels)

Regarding claim 2 Manz et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said fluid device is a microfluidic device, at least partly manufactured by micromachining methods. (See Abstract and C 1 L 32 -46)

Regarding claim 4 Manz et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein said control means is a cross-over channel. (See Fig. 3A and 3B where control means 304 is a channel and crosses over channels 322 and 318)

Regarding claim 5 Manz et al. discloses all the claim limitations as set forth above as well as a fluidic device wherein the cross-over channel divides two arrays of microchannels. (See Fig. 3B where cross-over channel divides arrays of microchannels 318 and 322)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over O' Connor et al. (US 6,481,453) as applied to claims 1-4, 6-18, and 20-24 above.

Regarding claim 19 O' Connor et al. discloses all the claim limitations as set forth above but does not specifically disclose a method wherein a plurality of consecutive independent sample fluid plugs are generated by repeating said steps of opening of said flush fluid inlet means and flush fluid outlet means by means of said valve means, flushing of said flush fluid control means with a flush fluid, transporting said sample liquid in said channels and said flush liquid in said flush fluid control means across said flush fluid control means further into said channels. It would have been obvious to one of ordinary skill in the art at the time of invention to generate subsequent plugs by repeating previously recited steps because mere duplication of parts or process steps

has no patentable significance, unless a new and unexpected result is produced, since it involves only routine skill in the art.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over O' Connor et al. (US 6,481,453) as applied to claims 1-4, 6-24 above, and further in view of Kennedy (US 5,876,675)

Regarding claim 13 O' Connor et al. discloses all the claim limitations as set forth above but does not disclose wherein the said fluidic device is arranged inside a compact housing, said housing being a diagnostic cartridge.

Kennedy discloses a fluidic device arranged inside a compact housing (See Fig. 1, 2, and C 8 L 42-62, C 9 L 12-44 where microfluidic device 102 is inserted into holder assembly), said housing being a diagnostic cartridge. (See C 2 L 26-4 and C 8 L 42-62 where device is used in diagnostic applications)

O' Connor and Kennedy are analogous because both references teach the use of microfluidic devices which include multiple channels. (See Kennedy C 5 L 13-20 and O' Connor Fig. 4B)

It would have been obvious to one of ordinary skill in the art at the time of invention to place the fluidic device of O' Connor in the structure of Kennedy because

doing so protects the fluidic device and prevents fouling, interference, and other adverse effects in the operation of microfluidic devices with material transport systems. (See Kennedy C 2 L 28-44 and C 5 L13-25)

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571)272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/

Primary Examiner, Art Unit 1797, & Art Unit 4153, TA

/J. M. H./

Examiner, Art Unit 4153